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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/945,425	10/21/97	CEDERBERG	1103026 202

WHITE & CASE  
PATENT DEPARTMENT  
1155 AVENUE OF THE AMERICAS  
NEW YORK NY 10036-2787

HM12/0430

EXAMINER  
DESAI, R

ART UNIT 1612 PAPER NUMBER 5

DATE MAILED: 04/30/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. <b>08/945,425</b>	Applicant(s) <b>Cederberg Christer et al</b>
	Examiner <b>Rita Desai</b>	Group Art Unit <b>1612</b>

Responsive to communication(s) filed on Apr 20, 1999

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 1-11, 15, 16, 18, and 19 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1-11, 15, 16, 18, and 19 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

*THE SINGLE DRAWING IS INFORMAL AND DOES NOT MEET THE REQUISITES OF 37 CFR 1.84 AND 1.85*

**-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --**

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## **DETAILED ACTION**

Claims 12-14 and 17 have been cancelled.

Claims 1-11,15,16,18 and 19 are pending.

1.

### ***Lack of Unity***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I , claims 1-11, 15,16,18 and 19 drawn to administration regimen, pharmaceutical formulations and method of treating , wherein Het1 is a substituted pyridine, and Het2 is a benzimidazole classified in Class 546 and 514 and Subclasses 273.4 and 339.

Group II , claims 1-11, 15,16,18 and 19 drawn to administration regimen, pharmaceutical formulations and method of treating , wherein Het1 is a substituted pyridine, and Het2 is an imidazo thiophene classified in Class 548 and 514 and Subclasses 303.7 and 339.

Group III, claims 1-11, 15,16,18 and 19 drawn to administration regimen, pharmaceutical formulations and method of treating , wherein Het1 is a substituted carbocyclic

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ring, and Het2 is an benzimidazole classified in various subclasses in Class 568 and 514.

Group IV, claims 1-11, 15,16,18 and 19 drawn to administration regimen, pharmaceutical formulations and method of treating , wherein Het1 is a substituted carbocyclic ring, and Het2 is an imidazo thiophene classified in various subclasses in Class 568, 548 and 514.

The inventions listed as Groups do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The common core of X-S=O is not novel and with the substitutions of different groups like pyridine , benzimidazole or imidazo-thiophene gives rise to numerous compounds with different bonding and chemical properties. The search for these compounds is not co-extensive, hence the search is burdensome.

These Groups are independent and distinct from one another as each group has achieved a separate status in the art, have fields of search which are not co-extensive and are capable of supporting separate patents.

During a telephone conversation with Mr. John Genova on April 21 1999 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-11, 15,16,18 and 19 drawn to administration regimen, pharmaceutical formulations and method of treating , wherein Het1 is a substituted pyridine, and Het2 is a benzimidazole classified in Class 546 and

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514 and Subclasses 273.4 and 339. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-11, 15,16,18 and 19 drawn to administration regimen, pharmaceutical formulations and method of treating , wherein Het1 and Het2 are other groups are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

2.

*Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Regarding claim1, the phrase "characterized by" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d). It is recommended that "wherein" is used instead.

The term "inhibitor having the formula I" is considered open. It is recommended "inhibitor of Formula I" be used.

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3.

***Claim Rejections - 35 USC § 102***

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-11, 15,16,18 and 19 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Bergstrand et al US 5,753,265 and 5,817,338.

Bergstrand et al '265 discloses the pharmaceutical multiple unit tableted dosage of compound or its single enantiomer. ( See the whole document, lines 4-17 of column 1 and claims 1-3,17, 18,21 and 22 of US. 5,753265)

4.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4a. Claims 1-11, 15,16,18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bregstrand et al US 5,753,265 and 5817,338.

Berstrand et al '265 teaches the compounds of formula I or its single enantiomer , used as H<sup>+</sup> , K<sup>+</sup> ,ATPase inhibitors for gastric disorders.The difference between the reference and the instant is that it the instant claims an extended blood plasma concentration profile.The blood plasma profile is the measured amount of the H<sup>+</sup> , K<sup>+</sup> ATPase inhibitors concentration. This is the

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experimental data. It would have been obvious to a person of ordinary skill in the art that extended release of the active ingredient would effect the blood concentration profile.

**4b.** Claims 1-11, 15,16,18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tyers B. US 5330982.

Tyers ' 982 teaches the use of Omeprazole as H<sup>+</sup>, K<sup>+</sup> ATPase inhibitor. It also teaches the use of oral administration suitably formulated to give controlled release.( See lines 53-56 of column 10, lines 42-43 and 60- 66 on column 2 of the reference.) The difference between the reference and the claimed invention is that the reference is silent about the blood plasma profile. A person of ordinary skill in the art would have been motivated to collect blood concentrations to test the extended release of the active ingredient.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. Desai whose telephone number is (703) -305-1868. The examiner can normally be reached on Monday to Friday from 8.00 am to 4.30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the supervisor, Mr. John Kight, can be reached on (703) 308-0204.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-1235 .

R.D.

April 22<sup>nd</sup> 1999.



ALAN L. ROTMAN  
PRIMARY EXAMINER